

AMENDMENT

In the Claims:

Please amend claims 1-8, 10, 11, 15, 33, 38, and 39, and cancel claims 14 and 30, without prejudice or disclaimer. Also, please add new claims 40-48 as follows:

Subt 1
1. (Amended) A method of detecting the presence of a target [BS106] polynucleotide indicative of breast disease in a test sample, comprising:
(a) contacting said test sample with at least one [BS106-specific] reagent polynucleotide comprising at least about 10 nucleotides that (i) specifically bind, and (ii) have at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO 1; SEQUENCE ID NO 2; SEQUENCE ID NO 3; SEQUENCE ID NO 4; SEQUENCE ID NO 5; and [or] complements thereof; and

a
(b) detecting the presence of said [target BS106] target polynucleotide indicative of breast disease in the test sample[, wherein said BS106-specific polynucleotide has at least 50% identity to a polynucleotide selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof].

2. (Amended) The method of claim 1, wherein said target [BS106] polynucleotide is attached to a solid phase prior to performing step (a).

Subt 2
3. (Amended) A method for detecting mRNA of [BS106] a target polynucleotide indicative of breast disease in a test sample, comprising:

(a) performing reverse transcription with at least one primer in order to produce cDNA;

(b) amplifying the cDNA obtained from step (a) to obtain an amplicon, said amplifying using [BS106 oligonucleotides as] sense and antisense primers wherein each primer comprises at least about 10 nucleotides that (i) specifically bind, and (ii) have at

least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO 1; SEQUENCE ID NO 2; SEQUENCE ID NO 3; SEQUENCE ID NO 4; SEQUENCE ID NO 5; and complements thereof; [to obtain BS106 amplicon;] and

(c) detecting the presence of said [BS106] amplicon in the test sample, wherein [the BS106 oligonucleotides utilized in steps (a) and (b) have at least 50% identity to a sequence selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof] presence of the amplicon indicates detection of the target polynucleotide indicative of breast disease in the test sample.

4. (Amended) The method of claim 3, wherein said target polynucleotide in the test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).

5. (Amended) The method of claim 3, wherein said [detection step] detecting comprises utilizing a detectable label capable of generating a measurable signal.

6. (Amended) A method of detecting a target [BS106] polynucleotide indicative of breast disease in a test sample suspected of containing said target polynucleotide, comprising:

(a) contacting said test sample with at least one [BS106 oligonucleotide as a] sense primer and [with] at least one [BS106 oligonucleotide as an] anti-sense primer wherein each primer comprises at least about 10 nucleotides that (i) specifically bind, and (ii) have at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO 1; SEQUENCE ID NO 2; SEQUENCE ID NO 3; SEQUENCE ID NO 4; SEQUENCE ID NO 5; and complements thereof, and amplifying to obtain a first stage reaction product;

(b) contacting said first stage reaction product with at least one [other BS106] oligonucleotide probe to obtain a second stage reaction product, with the proviso that the

[other BS106] oligonucleotide probe is (i) located 3' to the [BS106 oligonucleotides] sense and antisense primers utilized in step (a), (ii) [and is] complementary to said first stage reaction product, wherein the probe comprises at least about 10 nucleotides that (i) specifically bind, and (ii) have at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO 1; SEQUENCE ID NO 2; SEQUENCE ID NO 3; SEQUENCE ID NO 4; SEQUENCE ID NO 5; and complements thereof; and

a 1
(c) detecting said second stage reaction product as an indication of the presence of the target [BS106] polynucleotide indicative of breast disease in the test sample], wherein the BS106 oligonucleotides utilized in steps (a) and (b) have at least 50% identity to a sequence selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof].

7. (Amended) The method of claim 6, wherein said target polynucleotide in the test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).

8. (Amended) The method of claim 6, wherein said [detection] detecting step comprises utilizing a detectable label capable of generating a measurable signal.

Subt 4
a 2C 4
10. (Amended) A test kit useful for detecting [BS106] a target polynucleotide indicative of breast disease in a test sample, said test kit comprising a container containing at least one [BS106] reagent polynucleotide comprising at least about 10 nucleotides that (i) specifically bind, and (ii) have at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO 1; SEQUENCE ID NO 2; SEQUENCE ID NO 3; SEQUENCE ID NO 4; SEQUENCE ID NO 5; and [having at least 50% identity to a sequence selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or] complements thereof.

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11. (Amended) A purified polynucleotide [or fragment thereof derived from a BS106 gene, wherein said] comprising a polynucleotide [is capable of selectively hybridizing to the nucleic acid of said BS106 gene and has at least 50% identity to a sequence selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof] having at least about 10 nucleotides that (i) specifically bind, and (ii) have at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO 1; SEQUENCE ID NO 3; and complements thereof.

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15. (Amended) A recombinant expression system comprising a [nucleic acid] polynucleotide sequence that [includes an open reading frame] encodes a polypeptide [derived from BS106] said polynucleotide sequence operably linked to a control sequence compatible with a desired host, wherein said [nucleic acid] polynucleotide sequence encodes a polypeptide [has at least 50% identity to a sequence selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof] of at least 8 contiguous amino acids derived from SEQUENCE ID NO:16.

a⁴ Subt
33. (Amended) A composition of matter comprising a [BS106] polynucleotide [or fragment thereof], wherein said polynucleotide has at least [50% identity to a polynucleotide selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof] about 10 nucleotides that (i) specifically bind, and (ii) have at least 90% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO 1; SEQUENCE ID NO 3; and complements thereof.

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38. (Amended) [A] An isolated gene [or fragment thereof] which codes for a

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[BS106] protein, said protein comprising [which comprises] an amino acid sequence with at least [50%] 90% identity with SEQUENCE ID NO 16.

39. (Amended) [A] An isolated gene [or fragment thereof] comprising DNA having at least [50%] 90% identity with SEQUENCE ID NO 4 or SEQUENCE ID NO 5.

--40. The method of claim 1, wherein said reagent polynucleotide comprises at least about 12 nucleotides.

41. The method of claim 1, wherein said reagent polynucleotide comprises at least about 15 nucleotides.

42. The method of claim 1, wherein said reagent polynucleotide comprises at least about 20 nucleotides.

A6
43. The purified polynucleotide of claim 11, wherein said polynucleotide comprises a polynucleotide sequence of at least about 12 nucleotides.

44. The purified polynucleotide of claim 11, wherein said polynucleotide comprises a polynucleotide sequence of at least about 15 nucleotides.

45. The purified polynucleotide of claim 11, wherein said polynucleotide comprises a polynucleotide sequence of at least about 20 nucleotides.

46. The recombinant expression system of claim 15, wherein said polynucleotide sequence encodes a polypeptide of at least 10 contiguous amino acids derived from SEQUENCE ID NO:16.

47. The recombinant expression system of claim 15, wherein said polynucleotide sequence encodes a polypeptide of at least 15 contiguous amino acids derived from SEQUENCE ID NO:16.

48. The recombinant expression system of claim 15, wherein said polynucleotide sequence encodes a polypeptide of at least 20 contiguous amino acids derived from SEQUENCE ID NO:16.--

REMARKS

Introductory Comments

Claims 1-39 are pending. Claims 17-29, 31, 32, 34, 36 and 37 have been withdrawn from consideration. Claims 1-16, 30, 33, 35, 38 and 39 have been examined on the merits. Claims 14 and 30 have been canceled by this amendment. New claims 40-48 have been entered by this amendment.

The Examiner has rejected claims 14 and 30 under 35 U.S.C. §112, first paragraph, asserting that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner has rejected claims 1-16, 30, 33, 35, 38 and 39 under 35 U.S.C. §112, second paragraph, asserting that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Examiner has rejected claim 11-16, 33, 38 and 39 under 35 U.S.C. §102(b) asserting that the claim is anticipated by Adams, et al.,(GENBANK accession no AA340069, from Nature 377 (6547 Suppl.) 3-174 (1995)) and by Hillier, et al. (Accession no. R75793, 1995).

The Examiner has rejected claims 1-10 and 35 under 35 U.S.C. §103(a) as being